Research Site Experts

Bottlenecks of Study Start Up & Some Suggestions for Efficiencies

Christine Pierre
President
RxTrials
christine.pierre@rxtrialsinc.com
410-465-2455

RxTrials
Research Site Experts

Research Site Experts

Special Thanks…

The Clinical Trials Transformation Initiative (CTTI)

- A public/private partnership between the FDA and Duke (with much industry representations)
- Robert Califf, MD - Duke
- Briggs Morrison, MD - Astra Zeneca (Pfizer)
- Diana Abbott, PhD - Duke
- Jean Bolte RN – Duke
- And so many more!

Reasons for the Study

- Establish a baseline of actual time spent during various phases of the start up period
- Create effective approaches for improving the start up phase
  - Providing “norm” to those who want to benchmark against industry standards
  - The development of standard terms
  - Time points to be collected moving forward

RxTrials
Research Site Experts

Research Site Experts

Collaboration At It's Best

19 CTTI member organizations submitted retrospective data on site/study information between January 1, 2009 and January 1, 2010

- 2 academic
- 4 ARO/CRO
- 2 biotechnology
- 2 medical device
- 1 government
- 2 Investigator
- 6 pharmaceutical

What Was Collected

- Unique identifier as per their system
- Protocol ID
- Site type
- IRB type
- Therapeutic area
- Sponsor name
- The date the protocol was sent by the sponsor/CRO to the site
- The date the protocol was received by the site
- The date the protocol was submitted to the IRB
- The date of the IRB's final decision on the protocol
- The date the contract was executed
- The date the first patient was enrolled at that site

The Data Flowed In

- 10,673 lines of original data were received
- 5,396 lines of data (50.6%) were used
  - 64% Pharmaceutical companies
  - 13% ACRs/CROs
  - 10% Academic organizations
  - 10% Biotechnology
  - 3% Others

The Sites Represented

- 25.6% Academics
- 24.6% Private practices
- 6.6% Hospital-based
- 3.1% VA
- 39.2% Unknown

Therapeutic Representation

- 20.7% Hematology
- 19.1% Cardiovascular/metabolic
- 14.1% Other
- 13.4% Neurosciences
- 8.9% Allergy/respiratory
- 4.7% Pain
- 4.6% Inflammation

RxTrials
Research Site Experts

Research Site Experts

Some Realities Learned Early On

- Little standardization for **what is collected**
- Little standardization for **what it's called**
- Multiples places **where it's stored**

What Was Measured

The date the protocol was sent by the sponsor/CRO to the site against…

1. The date the protocol was received by the site
2. The date the protocol was submitted to the IRB
3. The date of the IRB's final decision on the protocol
4. The date the contract was executed
5. The date the first patient was enrolled at that site

*If absolute dates were not available, approximate dates were provided

*US sites only, Phase 2-4 multicenter trials

RxTrials
Research Site Experts

Research Site Experts

If You had to choose one factor that would be the strongest predictor of how long it will take a site to get up and going what would it be?

#1 - The Type of IRB Used

- Or maybe…
  - Is it really more about the **type of the sites and studies** that must utilize a local IRB and all that entails

RxTrials
Research Site Experts

Research Site Experts

IRB Process

Event	Median Time (days)	Significantly higher than median time (days)	Type of site higher than median site	Significantly lower than median time (days)	Type of site lower than the median site
Number of days between date protocol was received at site and date of protocol submission to IRB	44	51 66 68	VA Academic hospital-based	30 39	private practice independent sites
Number of days between IRB submission and IRB final decision	9	17 33 55	academic hospital-based VA	6 10	private practice independent
Central IRB decision	7				
Local IRB decision	35				

Then There's The Lawyers

Event	Median Time (days)	Significantly higher than median time (days)	Type of site higher than median site	Significantly lower than median time (days)	Type of site lower than the median site
Number of days between date protocol is received at site and date of contract execution	54	57 74 102 104	Independent academic VA hospital-based	35	Private practices

RxTrials
Research Site Experts

Research Site Experts

The One Everyone Loves to Measure

Event	Median Time (days)	Significantly higher than median time (days)	Type of site higher than median site	Significantly lower than median time (days)	Type of site lower than the median site
Number of days between IRB final decision and date of FPFV	80	89 102	Private practice hospital-based	70 72	VA & independent Academic
Central IRB	74 days				
Local IRB	95 days				

RxTrials
Research Site Experts

Research Site Experts

1st subject consented within …

- 30 days = 90+% chance of success
- 60 days = 50% of success
- 90 days = <10% chance of success

Source: AAIPharma 2005

RxTrials
Research Site Experts

Research Site Experts

Take Aways

- Data that does not reside in one central location within a company places a challenges upon anyone to measure and act upon it
- A lack of industry standards regarding the terms or milestones to measure creates continued inefficiencies
- The use of a central IRB results in the site's approval 27 days sooner than a local IRB
- The site that uses a central IRB enrolls their first subject 21 days sooner than a site that uses a local IRB
- We're not done…

  Prospective study to follow

Research Site Experts

Thank You

Christine Pierre
President
RxTrials
christine.pierre@rxtrialsinc.com
410-465-2455